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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,731	09/27/2005	Vesna Skulj	RG/G-32919A	3189

83721 7590 06/23/2009

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EXAMINER	
KARPINSKI, LUKE E	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
06/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,731	SKULJ ET AL.	
	Examiner	Art Unit	
	LUKE E. KARPINSKI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-12 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-12, and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Change in Examiner

The examination of this application will further be performed by Luke Karpinski; contact information can be found at the end of this action.

Claims

Claims 2, 3, 13, and 14 are canceled.

Claims 18-20 are new.

Claims 1, 4-12, and 15-20 are currently pending and under consideration in this action.

Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-12, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zmitek et al. (US Pat. 5,498,788) in view of Buckton et al., Sherwood et al. (US Pat. 5,585,115) and Czap.

Zmitek et al. disclose a rapidly disintegrating tablet containing potassium clavulanate, amoxicillin trihydrate, magnesium stearate and microcrystalline cellulose (MCC) which is prepared y homogeneously mixing the ingredients, sieving and tableting (Column 11, lines 5-31).

Buckton et al. disclose that silicified microcrystalline cellulose (SMCC) has advantages over conventional MCC in tableting in that it has superior flow properties (Abstract).

Sherwood et al. disclose that SMCC possesses excellent disintegration properties and is free-flowing, has improved compressibility versus standard commercially available MCC and has higher tablet strength versus MCC (Column 4, lines 34-68, Column 5, lines 1-10, Column 11, lines 34-45, Column 15, lines 36-68, Column 16).

Czap disclose that hydrogenated castor oil is used as a lubricating aid in tablets similar to stearic acid or stearic acid complexed with magnesium (See Editorial).

The prior art discloses a rapidly disintegrating tablet containing potassium clavulanate, amoxicillin trihydrate, magnesium stearate and microcrystalline cellulose which is prepared y homogeneously mixing the ingredients, sieving and tableting. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of SMCC or hydrogenated castor oil. However, the prior art amply suggests the same as the prior art discloses that silicified microcrystalline cellulose and hydrogenated castor oil are excipients used

in tableting. As such, it would have been well within the skill of one of ordinary skill in the art to modify the prior art as above with the expectation that substitution of silicified microcrystalline cellulose would facilitate the tableting process and that hydrogenated castor oil would be a suitable substitute for magnesium stearate as a lubricating aid in the tableting process.

Response to Arguments

Applicant's arguments filed 8/07/2008 have been fully considered but they are not persuasive.

Applicant argues that crospovidone is a superdisintegrant, as found in Zmitek et al., and therefore Zmitek et al. does not teach the instant invention.

This argument is not found persuasive because Zmitek et al. also teach that said disintegrants are optional ingredients (col. 6, lines 5-12). Therefore it would have been obvious to not utilize crospovidone in example 10. Further, applicant claims that said compositions comprise of substantially no superdisintegrant. Applicant, however, fails to define substantially no within the specification and therefore one of skill would have no idea to what extent 'substantially no' refers. Therefore the amount taught by Zmitek et al. is deemed to read on substantially no, as applicant has not defined said phrase.

The Applicant argues that the Buckton reference would not have lead a person of ordinary skill in the art to substitute SMCC in place of MCC because Buckton discloses that the SMCC has a higher tablet strength and higher compressibility after wet granulation. However, the Applicant has not provided any evidence that this difference would result in tablets incapable of rapidly disintegrating or that one of ordinary skill in the art would have considered higher

tablet strength and higher compressibility after wet granulation to be drawbacks to rapidly disintegrating tablets. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). In any case, as indicated in Sherwood et al. above, SMCC has excellent disintegration properties. As such, the Applicant has not shown that the higher tablet strength and compressibility after wet granulation of SMCC versus MCC are drawbacks to rapid tablet disintegration.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zmitek et al. (US Pat. 5,498,788) in view of Buckton et al., Sherwood et al. (US Pat. 5,585,115) and Czap.

Applicant Claims

Applicant claims the tablet of claim 1 further comprising 1500mg of active substance and wherein none of said components are granulated.

Applicant also claims the process of claim 17 wherein the step of forming said tablets comprises direct compression.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of all prior art are delineated above and incorporated herein. In particular Zmitek et al. teaches tableting with a rotary tableting machine (col. 11), which utilizes direct compression, as pertaining to claim 18, about 1400mg per tablet of active substances (example 10), as pertaining to claim 19, and that a mixture of said amoxicillin, clavulanic acid and MCC were obtained in dry powder form prior to tableting (col. 12), as pertaining to claim 20.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Zmitek et al. do not teach the absence of granulation as claimed in claim 20. This deficiency is cured by Zmitek itself, which teaches that said mixtures are obtained in dry powder form prior to tableting, granulation, and sieving.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Regarding the limitation of granulation, it would have been obvious to not briquette and granulate the compositions of Zmitek et al. in order to produce the formulations of claim 19.

One of ordinary skill in the art would have been motivated to do this because there is no need to briquette and then later granulate a powder composition unless there is a storage or shipping step, wherein handling said compositions as briquettes may be easier. The formulations of Zmitek et al. were already in powder form and one of ordinary skill in the art would have readily seen that said powder compositions could bypass the briquetting and granulation steps and proceed immediately to the sieving and tableting steps. Therefore it would have been obvious to not granulate the compositions of Zmitek et al. Further, claim 19 is seen as a product by process claim and upon no showing that the process results in a materially different product, the products as viewed as the same. The steps of briquetting and granulating said compositions would result in no difference in final product and therefore said limitation bears little weight on the claim itself. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the

product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 2, 3, 13, and 14 are canceled.

Claims 1, 4-12, and 15-20 are rejected.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

/Mina Haghighatian/
Primary Examiner, Art Unit 1616